K134010

APR 1 4 2014

5.0 510(k) SUMMARY

Owner and Official Correspondent:	Cabochon Aesthetics, Inc. 127 Independence Drive Menlo Park, CA 94025 Contact: Ben F. Brian, Ph.D., President & CEO Telephone: 650-906-0874 Facsimile: 650-543-0732 Email: bbrian@cabochoninc.com
Date of Preparation:	March 3, 2014
Device Trade Name:	Cabochon System
Common Name:	Powered surgical instrument for improvement in the appearance of cellulite.
Classification:	II
Classification Name:	Powered surgical instrument for improvement in the appearance of cellulite (21CFR 878.4790)
Product Code:	OUP
Legally Marketed Predicate:	Cabochon System, 510(k): K101231
Device Description:	The Cabochon System is the same (identical) device as the legally marketed predicate and intended to provide precise focal release of subcutaneous tissue for improvement in the appearance of cellulite. The release of subcutaneous tissue for improvement in the appearance of cellulite is a minimally invasive surgical technique by physicians using a variety of manual surgical instruments and accessories. The Cabochon device consists of a powered cutting blade and a means for instrument guidance to control the depth, size and shape of the area of the tissue release.
Indications for Use:	The Cabochon System is intended for long term improvement in the appearance of cellulite in the buttocks and thigh areas of adult females as supported by clinical data demonstrating no significant reduction in treatment benefits up to 1 year of observation.
Predicate Indications for Use:	The Cabochon System is intended for the short term improvement in the appearance of cellulite in the buttocks and thigh areas of adult females.
Explanation of Differences	The Cabochon System is the same (identical) device as the legally marketed predicate cleared (K101231) on July 12, 2013 following completion of the review of the Request for Evaluation of

Automatic Class III Designation (*de novo* Petition) for the Cabochon System. Reclassification to Class II (special controls) was supported by the 3 month clinical data from the pivotal study conducted under IDE G120116. The reason for this submission is to request change in indications for use based on 1 year follow-up and independent evaluation of safety and effectiveness in the pivotal study (IDE G120116). These differences are not critical to the intended use of the device and do not affect the safety and effectiveness of the device when used as labeled.

Performance Testing:

Bench

Comprehensive bench testing has been successfully completed for the Cabochon System on multiple lots of aged and time-zero product. Testing was performed on finished, sterile devices that were exposed to environmental and transportation conditioning prior to testing which included simulated use, durability and mechanical integrity. All devices were shown to meet pre-determined acceptance criteria.

Animal

Ex vivo and *in vivo* studies were conducted in the porcine model to verify the performance of the Cabochon System. The *ex vivo* studies used sections of porcine tissue excised from the sides of Yucatan pigs. The tissue sections were harvested from euthanized pigs and consisted of the dermis, fat, and muscle layers extending down to the rib cage. Verification of the depth of tissue release and the release area was performed in this model.

The *in vivo* studies were performed on Yucatan pigs under general anesthesia to verify the safety of the release methodology. Treatment with the Cabochon System was performed at different treatment time points prior to euthanasia to investigate the healing response. Findings included that bleeding was minor at all the treatment sites, the plane and areas of tissue release were within specification and the area of release was as expected. There were no necrotic areas noted in the dermis at any time point, as determined by gross and histological evaluation.

Clinical

The safety and effectiveness of the Cabochon System was evaluated in a pivotal clinical study conducted under IDE G120116. A prospective, multi-center, non-randomized open label, safety and effectiveness study with treatment of 55 subjects was conducted in 3 US centers. All subjects served as their own control and underwent a single treatment with the Cabochon

System. All subjects underwent follow-up assessments at 3 days, 14 days, 1 month, 3 months, 6 months and 1 year post treatment. The subject inclusion/exclusion criteria limited inclusion to female subjects between the ages of 18 and 55 with moderate to severe cellulite and BMI less than 35. The subjects were asked to rate their satisfaction with their appearance and pain. Photographs were taken in accordance with a protocol-specific procedure at baseline and each follow-up. An independent and blinded review of the photographs before treatment and at 1 year was used to verify the effectiveness of the procedure. A DSMB was formed and independently managed to provide safety oversight for the study.

All study endpoints were achieved. The primary safety endpoint, defined as freedom from serious adverse events attributable to the Cabochon procedure or device was achieved for all subjects (100%). The overall study success criteria was met with a clinically significant, long term improvement in the appearance of cellulite in the treated subjects defined by the following:

- The primary endpoint was met: achievement of $\geq$1 point average reduction in the 0-5 point Cellulite Severity Scale as determined by independent physician assessment of subject photographs taken before and 1 year after treatment.
    - The average improvement was 2.0 points ($p<0.0001$) with the 97.5% confidence limit of a 1.7 point improvement.
- The powered secondary endpoint was met: improvement of one grade or more in severity (none, mild, moderate, severe) in >60% of treated subjects as determined by independent physician assessment of subject photographs taken before and 1 year after treatment.
    - 94.0% of treated subjects had improvement of 1 grade with a 95% confidence limit of 85.9%.

All additional secondary measures were also achieved or acceptable:

- The average rate of correct selection by independent physician assessment of blinded subject photographs taken before and 1 year after treatment was 99%.
- 100% of the subjects had noticeable improvement in the Global Aesthetic Improvement Scale GAIS and 72% were characterized as having marked improvement or better by independent physician assessment of blinded subject

photographs taken before and 1 year after treatment.

- 94% of the subjects were either satisfied or very satisfied as evaluated by a 5 point Likert type scale at the 1 year follow-up.
- Subject reported pain on a 0-10 numerical rating scale was 4.5 for the delivery of anesthesia and 3.7 for the tissue release portion of the procedure. For the follow-ups, 71% of subjects rated pain ≤ 3 at 3 days, and over 95% rated pain ≤ 3 thereafter. No subjects reported pain at 1 year.

Conclusion:

The (only) purpose of this 510(k) Premarket Notification is for updated labeling of the Cabochon System based on the completion of the 1 year follow-ups from the pivotal study. This clinical data demonstrates that the Cabochon System is both safe and effective for long term improvement in the appearance of cellulite. Based on the design, materials, principle of operation and intended use, the Cabochon System is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 14, 2014

Cabochon Aesthetics Incorporated
Ben F. Brian, Ph.D.
President & Chief Executive Officer
127 Independence Drive
Menlo Park, California 94025

Re: K134010
Trade/Device Name: Cabochon System
Regulation Number: 21 CFR 878.4790
Regulation Name: Powered Surgical Instrument For Improvement In The Appearance Of Cellulite
Regulatory Class: Class II
Product Code: OUP
Dated: January 16, 2014
Received: January 17, 2014

Dear Dr. Brian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 INDICATIONS FOR USE

510(k) Number: K134010

Device Name: Cabochon System

Indications for Use:

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Type of Use

☒ Prescription Use
(Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED)

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S